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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/852,965      | 05/10/2001  | Scott F. Sneddon     | 2478,1002-002       | 4903             |

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1624     |              |

DATE MAILED: 05/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                     |
|------------------------------|--|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>                   | <b>Applicant(s)</b> |
|                              | 09/852,965                               | SNEDDON ET AL.      |
|                              | Examiner<br>Venkataraman Balasubramanian | Art Unit<br>1624    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 January 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) 1-14,33-70 and 101-107 is/are withdrawn from consideration.
- 5) Claim(s) 31 and 32 is/are allowed.
- 6) Claim(s) 15-20,23,30 and 71-100 is/are rejected.
- 7) Claim(s) 21,22 and 24-29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 &amp; 7</u> . | 6) <input type="checkbox"/> Other: _____                                     |

### **DETAILED ACTION**

Applicant's election of Group V, drawn to claims 15-32 and 71-100 in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14, 33-70 and 101-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected groups.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of the phrase "composition of matter" in claim 30 is deemed as indefinite as implies more than what is being positively recited. Note the claim is a pharmaceutical composition claim not "of matter comprising the active compound". Deletion of "of matter" is suggested.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Biedermann et al. DE 29 37 698.

Biedermann et al. teaches several propionylsarcosinylanilides, which include compounds, claimed in the instant claims. See formula I on page 1 and note the definition of A. See also page 8and 9 for teaching of various substituted aniline for making the anilide of formula I. See examples 1-5 on pages 10 to 14.

Claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayer et al. Chem. Ber., 103(8) 2581-2597, 1970 (CAPLUS Abstract provided).

See benzamide compound shown (RN 28544-59-4).

Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hazebroucq et al. Ann.Chim (Paris) 1(5/6), 221-254, 1966 (CAPLUS Abstract provided).

See acetanilide compound shown (RN 14174-520-0).

Claim 15 IS rejected under 35 U.S.C. 102(b) as being anticipated by Spies et al. WO 95/12610.

Spies et al. teaches several N-alkyl peptide as chelating agents, which include compounds claimed in the instant claims. See examples shown on pages 38-40, example 7 on page 46 and example 11 on page 48.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al. US 4,997,950.

Murphy et al. teaches several N-alkyl peptides as gastrin antagonists, which include compounds claimed in the instant claim. See compounds shown on col. 37 and 38, especially compound XIV and XVI. See the same in Table 6.1 on col. 46.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter et al US 6,048,841.

Baxter et al. teaches several peptidyl compounds for treating diseases mediated by tumor necrosis factor. See Formula I, on col. 1 and note the definition of various

variable groups. Note the process for making shown on col. 4 and col. 5. See examples 1-9 for compounds made shown on col. 12-13.

While said compound doesn't anticipate the scope of the instant claims they are very closely related, being NH vs having a methyl group on the ring nitrogen in the instant compounds. See instant R<sup>10</sup>. However, compounds that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me on nitrogen, see Ex parte Weston 121 USPQ 428; In re Doebele 174 USPQ 156. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 15-20, 23 and 71-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. US 5,932,737 in view of Baxter et al US 6,048,841.

Itoh et al. teaches large number of peptide compounds for treatment of NO-mediated diseases, which include generically compounds claimed in the instant claims.

See formula I on col. 1 and note W-A<sup>1</sup> definition corresponds to instant COR<sub>11</sub>, R<sup>8</sup> to instant R<sub>10</sub>, the A<sup>2</sup>-T group to instant R<sub>9</sub> and R<sup>9</sup>, CH(A<sup>3</sup>-R<sup>3</sup>)R<sup>4</sup> to instant R<sub>8</sub>, R<sub>12</sub>. See process of making these compounds on col. 4 through col. 8. See col. 32 through 490 for compounds made. Especially see col. 125, preparation 60(160, which teaches N-methyl phenylalanine peptide. For method of use see col. 1, lines 34-50 and col. 18 lines 5-24.

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Instant claims 15-20 and 23 differ from the reference in specifically requiring R<sub>10</sub> to be substituted but not hydrogen as taught in the examples of Itoh et al.

However Itoh et al. teaches the equivalency of exemplified substituents hydrogen with alkyl claimed in the definition of corresponding R<sup>8</sup>. See col. 1 and 2 formula I, especially the definition of R<sup>8</sup>. Itoh et al. teaches the contemplated N-methyl phenylalanine bearing peptide as noted above.

Claims 71-100 recite method of use of instant compounds for TNF-mediated conditions while Itoh et al. teaches use for the compounds for various diseases, which include those claimed in the instant method of use claims. Note difference in mode of action as TNF- $\alpha$  mediated condition versus NO mediated conditions are irrelevant to the treatment of the disease.

In addition, the secondary reference Baxter et al. clearly teaches use of structurally related compounds for TNF- $\alpha$  mediated conditions.

Thus one would be motivated to combine the teaching of the primary and the secondary references. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in nitrogen including alkyl groups ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

#### ***Allowable Subject Matter***

Claims 31-32 are allowed. Claims 21-22, 24-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.

Said claims would be allowed since specific species embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Information Disclosure Statements (paper # 4 & 7) are made of record.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 5.30 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*V. Balasubramanian*  
Venkataraman Balasubramanian

5/18/2002